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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,988	02/05/2004	Snorri S. Thorgeirsson	11613.29USD1	5511

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EXAMINER	
DAVIS, MINH TAM B	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,988	THORGEIRSSON ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment: See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-3. Claims 1-7, 21, 23, drawn to a BOG polypeptide, SEQ ID NO: 2 (rat), SEQ ID NO:8 (human), or SEQ ID NO:10 (murine), or a fragment thereof, a chimeric molecule, classified in class 530, subclass 350. Each BOG polypeptide constitutes a single, distinct invention.

Groups 4-6. Claims 8-20, 22 drawn to a nucleic acid encoding a BOG polypeptide, SEQ ID NO: 2 (rat), SEQ ID NO:8 (human), or SEQ ID NO:10 (murine), or a fragment thereof, an antisense, a vector, a host cell, a process for producing a BOG polypeptide, classified in class 536, subclass 23.1. A nucleic acid encoding each BOG polypeptide constitutes a single, distinct invention.

Groups 7-9. Claims 24-26, drawn to an antibody specific for a BOG polypeptide SEQ ID NO: 2 (rat), 8 (human), or 10 (murine), or a fragment thereof, classified in class 530, subclass 387.1. An antibody specific for each BOG polypeptide constitutes a single, distinct invention.

Groups 10-12. Claim 27, drawn to a method of assaying for a polynucleotide encoding a BOG polypeptide SEQ ID NO: 2 (rat), 8 (human), or 10 (murine), or a fragment thereof, classified in class 435, subclass 6. A method using each BOG polynucleotide constitutes a single, distinct invention.

Groups 16-18. Claims 29-30, drawn to a method for reducing BOG nucleic acid expression, or inducing apoptosis, using an antisense, classified in class 514, subclass 44. A method using each of the BOG polynucleotide constitutes a single, distinct invention.

Groups 19-21. Claim 31, drawn to a method for producing cell lines having altered phenotype, using a vector encoding BOG polypeptide SEQ ID NO: 2 (rat), 8 (human), or 10 (murine), or a fragment thereof, classified in class 435, subclass 69.1. A method using each of the BOG polynucleotide constitutes a single, distinct invention.

Groups 22-24. Claim 32, drawn to a method for inhibiting interaction between a pRb A/B domain binding protein, and a pRb family member, using a BOG polypeptide SEQ ID NO: 2 (rat), 8 (human), or 10 (murine), or a fragment thereof, classified in class 514, subclass 2. A method using each of the BOG polypeptide constitutes a single, distinct invention.

The inventions are distinct, each from each other because of the following reasons:

A. Inventions (1-3), (4-6), and (7-9) represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects.

The polypeptides of groups 1-3, the polynucleotides of groups 4-6, and the antibodies of groups 7-9 are all structurally distinct molecules and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, while the polypeptide is made by translation of mRNA, and the antibody is made by expression of a hybridoma. Further, the polynucleotide can be used for hybridization screening, the polypeptide can be used for methods of treatment, and the antibody can be used for antibody binding detection. Furthermore, neither of the inventions is

essential for the production of the other, and they have different modes of operation, different functions, and different effects. While a polypeptide can made by methods using the corresponding polynucleotide, it can also be recovered from a natural source using biochemical means. For instant, the polypeptide can be isolated, using affinity chromatography. Similarly, the antibody can be isolated from natural source, using biochemical means..

Further, it is noted that for unity of invention, the compounds have to (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential for that utility. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). In the instant application, the different sequences do not share a substantial structure feature disclosed as being essential for treating cell proliferation.

Searching all the polypeptides of groups 1-3 together, the polynucleotides of groups 4-6 together, or all the antibodies of groups 7-9 would cause serious burden. In the instant case, the search of all the polynucleotides, the polypeptides or the antibodies are not coextensive. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to one polynucleotide which would not have described other polynucleotides, or the polypeptide, or the antibody thereof. Similarly, there may be journal articles devoted solely to the antibody, which would not have described the polypeptide, or the polynucleotide. Further, an amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies . Furthermore, antibodies, which bind to an epitope of a polypeptide may be known even if a polypeptide is novel.

As such, it would be burdensome to search the inventions of Groups 1-3, 4-6, 7-9 together.

B. The inventions of Groups 10-24 are materially distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, and different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The inventions of Groups 10-24 are materially distinct methods, which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Further, the method of assaying BOG polynucleotide or polypeptide, a method of inducing apoptosis, a method for producing a cell line with altered phenotype, a method for inhibiting interaction with a pRb family member are all unrelated as they have different modes of operation, and differ in method steps and reagents used. For detecting a polypeptide, quantitation of a labeled antibody that binds specifically to said polypeptide may be used. For detecting a polynucleotide, hybridization assay may be used. For inducing apoptosis, the BOG polynucleotide is administered to a patient having the disease, using any mode of administration. For producing a cell line with altered phenotype, a vector encoding the BOG polypeptide is administered to the cells. For inhibiting interaction with a pRb family member, a BOP polypeptide is administered. Thus, each group is unrelated as they comprise distinct steps and utilize different products, which demonstrates that each method has different mode of operation. Moreover, different products used in the different methods, which are distinct because they are different polynucleotides or polypeptides with distinct structure and function, would produce different effects. For these reasons the Inventions 10-24 are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. The examination of all groups would require different searches in the U.S. patent shoes and the scientific literature and would require the consideration of different patentability issues. There may be journal articles devoted solely to detecting the presence of a BOG polypeptide, or a BOG polynucleotide, which would not have described methods of detecting the presence of another BOG polypeptide, or another BOG polynucleotide, or a method of inducing apoptosis, a method for producing a cell line with altered phenotype, method for inhibiting interaction with a pRb family member , or vice versa . Moreover, even if the method for detecting a BOG polynucleotide were known, the method of inducing apoptosis, using the same products may be novel and unobvious, in view of the preamble and active steps.

As such, it would be burdensome to search the inventions of Groups 10-24 together.

C. The invention of Groups (1-3) and the methods of Groups (13-15, 22-24) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product (see MPEP 806.05(h)). In the instant case the polypeptides product as claimed can be used in a materially different process such as in making an antibody, in addition to treating a disorder.

Searching the inventions of Groups (1-3) and Groups (13-15, 22-24) together would impose serious search burden. The inventions of Groups (1-3) and Groups (13-15, 22-24) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the searches for the BOG polypeptide and the method of detecting a BOG polypeptide, or the

method for inhibiting interaction with a pRb family member, using the polypeptide are not coextensive. The search for Groups (13-15, 22-24) would require a text search for the method of detecting a BOG polypeptide, or the method for inhibiting interaction with a pRb family member, in addition to a search for the polypeptide. Moreover, even if the polypeptide product were known, the method of detecting a BOG polypeptide, or the method for inhibiting interaction with a pRb family member, which uses the product may be novel and unobvious, in view of the preamble or active steps.

D. The invention of Groups (4-6) and the methods of Groups (10-12, 16-18, 19-21) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product (see MPEP 806.05(h)). In the instant case the polynucleotides product as claimed can be used in a materially different process such as in making the polypeptide, in addition to treating diseases.

Searching the inventions of Groups (4-6) and Groups (10-12, 16-18, 19-21) together would impose serious search burden. The inventions of Groups (4-6) and Groups (10-12, 16-18, 19-21) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotide and the method of detecting the polynucleotide, a method for inducing apoptosis, or a method for producing a cell line having altered phenotype are not coextensive. The search for Groups (10-12, 16-18, 19-21) would require a text search for the method of detecting the polynucleotide, a method for inducing apoptosis, or a method for producing a cell line having altered phenotype, in addition to a search

for the polynucleotide sequence of groups (4-6). Moreover, even if the polynucleotide product were known, the method of detecting the polynucleotide, a method for inducing apoptosis, or a method for producing a cell line having altered phenotype, which uses the product may be novel and unobvious, in view of the preamble or active steps.

E. The inventions of Groups (7-9) and Groups (13-15) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody binding agent can be used to make affinity column, as opposed to treating a disorder.

Searching the inventions of Groups (7-9) and Groups (13-15) together would impose serious search burden. The inventions of Groups (7-9) and Groups (13-15) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the antibody and the method of detecting a BOG polypeptide, using the antibody, are not coextensive. In addition, the search for Groups (13-15) would require a text search for the method of detecting a BOG polypeptide, in addition to a search for the antibody. Moreover, even if the antibody product were known, the method of detecting a BOG polypeptide, which uses the product may be novel and unobvious in view of the preamble or active steps.

F. Inventions of Groups (1-3, 7-9) and Groups (10-12, 16-18, 19-21) are unrelated because the product of groups (1-3, 7-9) is not used or otherwise involved in the processes of groups (10-12, 16-18, 19-21).

Inventions of Groups (4-6) and Groups (13-15, 22-24) are unrelated because the product of groups (4-6) is not used or otherwise involved in the processes of groups (13-15, 22-24).

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be

amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS
September 27, 2006

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER